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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,364	THULA, TAILI TEE	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1 and 4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 2, 3, and 8-12, filed June 24, 2009 is acknowledged and has been entered. Claims 1 and 4-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-12 are pending. Claims 2, 3, and 8-12 are and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 3, and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 in the preamble is indefinite in reciting, "determining the proper dosage for an anticoagulant" because the term "proper" is a relative term that lacks a comparative basis for defining its metes and bounds.

Claim 2 is vague and indefinite in reciting, "vitamin K nutritional status [of a patient]" in its first occurrence and second occurrence because "nutritional status"

appears to be a subjective term that lacks a comparative basis for defining its metes and bounds. See also claim 3.

Claim 2, line 2, lacks clear antecedent basis in the recitation of “the dosage.”

Claim 2, line 2, has improper antecedent basis in the recitation of “an anticoagulant.”

Claim 3, line 2, lacks clear antecedent basis in the recitation of “the expected effects of certain nutritional values for vitamin K.” Additionally, the term "certain" is a subjective term that lacks a comparative basis for defining its metes and bounds.

Regarding claim 3, the phrase "expected effects" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "expected effects"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 3 is also ambiguous in reciting, “diet patterns” because it is unclear what Applicant intends to encompass in reciting “diet patterns.” Does the recitation encompass factors such as time or regularity of food intake, amount of food intake, type of food intake?

Claim 8, in the preamble lacks antecedent basis in reciting, “said device."

Claim 8, part (2) is indefinite in lacking clear antecedent basis for the recitation of "analyte in said sample" since the preamble appears to have recited "a liquid sample suspected of containing a Vitamin K marker." It is therefore, unclear as to whether the “analyte” in step (2) should be the same as the "Vitamin K marker." Alternatively, claim

8 is unclear as to the essential structural and/or functional cooperative relationship between the recited “analyte” and the recited “Vitamin K marker.”

Claim 8, part (3) is also indefinite in lacking clear antecedent basis for "said analyte" since the preamble appears to have recited "a liquid sample suspected of containing a Vitamin K marker." It is therefore, unclear as to whether “said analyte” in step (3) should be the same as the "Vitamin K marker." Alternatively, claim 8 is unclear as to the essential structural cooperative relationship between the recited “analyte” and the recited “Vitamin K marker.”

Claim 12 is ambiguous in reciting, “the presence of Vitamin K marker produces a detectable signal" because it fails to clearly define how the detectable signal is specifically produced based on the recited elements or components in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sokoll et al. (Undercarboxylated Osteocalcin and Development of a Method to Determine Vitamin K Status, Clin. Chem. 41 (8): 1121-1128 (1995)).

Sokoll et al. examined and teach the effect of anticoagulant (minidose warfarin, i.e. Vitamin K antagonist) on levels of Vitamin K nutritional status of patients by way of

measuring carboxylated, i.e. undercarboxylated, osteocalcin (Vitamin K marker) in a patient's blood serum or plasma sample. Sokoll et al. specifically teach using polyclonal antibody specific for carboxylated osteocalcin to measure the vitamin K1 level in the patient's blood sample (Abstract; p. 1121, col. 2; p. 1122; p. 1123, col. 1; Figure 6). Sokoll et al. found that the percentage of undercarboxylated osteocalcin increased after 7 days of treatment with 1 mg/day dosage of anticoagulant warfarin (Figure 1; page 1124, col. 2, last full par. to p. 1125, col. 1). Sokoll et al. also established and determined that undercarboxylated osteocalcin is effective as a sensitive Vitamin K marker that measures Vitamin K nutritional status by observing a decrease in concentration of the undercarboxylated osteocalcin below baseline with 2 days of Vitamin K1 repletion at 5 mg/day (Abstract; page 1121, col. 1; p. 1123, col. 1; Figure 6). Accordingly, Sokoll et al. is deemed to teach that the dosage of warfarin anticoagulant can be modulated based on the amount of vitamin K measured from the patient, whereupon the anticoagulant dosage is increased, decreased, or maintained based on the vitamin K intake or nutritional status of patients.

4. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (US Patent 6,352,862)

Davis et al. disclose a diagnostic reagent unit or device (analytical test device) having a dry porous carrier strip for analyzing a liquid sample suspected of containing an analyte (Abstract; col. 7, line 5 to col. 8, line 64; col. 9, line 32 to col. 11, line 63). The device has a liquid sample application member used to apply or introduce the liquid

sample into the device (Figure 1:106; Figure 2:106; col. 9, lines 36-47). The device also has a liquid sample receiver (macroporous body) which is a compartment containing labeled specific binding reagent or antibody specific to the analyte which is retained in a dry state. The liquid sample receiver in the form of the macroporous body is the portion to which the liquid sample is applied and passed en route to the dry porous carrier strip. The labeled specific binding reagent or antibody specific to the analyte is freely soluble so as to be mobile or dispersed in the liquid sample solution upon entry into the liquid sample receiver. The labeled specific binding reagent or antibody binds to the analyte, if present, during immunoassay (col. 1, line 53 to col. 2, line 15; col. 3, lines 7-30; col. 4, lines 14-26; Figure 2:113). The device also has a dry porous carrier (chromatographic, nitrocellulose) strip located downstream of the liquid sample receiver, wherein the dry porous carrier strip is a detection zone having unlabeled permanently immobilized specific binding reagent or antibodies also specific to the analyte and which also bind to the analyte, if present, and participate in a competitive or sandwich immunoassay format (col. 2, lines 30-49; col. 4, lines 27-43; Figure 2:114). The detection zone in the dry porous carrier strip provides a measure of the amount of analyte present in the liquid sample by generating a detectable signal that is measured instrumentally by an analyzer(col. 3, lines 1-2).

In as far as the recitation of “for analyzing a liquid sample suspected of containing a Vitamin K marker”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In as far as the recitation of "wherein said analyte is a Vitamin K marker," it is noted that such interpretive clause does not recite any additional structure to the claimed product to render it structurally distinct from the prior art. Therefore, such "wherein" clauses are not found to further limit the product defined by the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim.").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US Patent 6,352,862) in view of Sokoll et al. (Clin. Chem. 41 (8): 1121-1128 (1995)).

Davis et al. is discussed supra,

Davis et al. differ from the instant invention in failing to teach that the analyte is a Vitamin K marker which is carboxylated osteocalcin.

Sokoll et al. is discussed supra. Sokoll et al. specifically teach anti-carboxylated osteocalcin antibody as binding reagent for binding and detecting the presence of carboxylated osteocalcin in a patient sample. Sokoll et al. specifically teach using polyclonal antibody specific for carboxylated osteocalcin to measure the vitamin K1 level in the patient's blood sample (Abstract; p. 1121, col. 2; p. 1122; p. 1123, col. 1; Figure 6).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the labeled and unlabeled antibodies in the diagnostic reagent unit taught by Davis with polyclonal antibody specific for carboxylated osteocalcin to measure the vitamin K1 level in a patient's blood sample as taught by Sokoll because Davis is generic in his broad teaching of utility of the device for application with any analyte including proteins required to be detected in a blood sample and Sokoll taught that anti-carboxylated osteocalcin antibody has specific binding, specific affinity, and can be labeled for detection of carboxylated osteocalcin, a Vitamin K marker. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the teaching of Vitamin K markers of Sokoll in using anti-carboxylated osteocalcin antibody as binding reagent into the device of Davis because Davis specifically taught that the compact diagnostic reagent unit provides advantage in enhacing sensitivity, performance capability, ease of manufacture, as well as convenience in performing immunological assays for a wide variety of analytes including proteins, haptens, immunoglobulins, hormones, steroids, and drugs by simple appropriate choice of specific binding partners such as anti-carboxylated osteocalcin

antibodies as taught and used by Sokoll to monitor Vitamin K intake levels for incorporation into the device.

6. No claims are allowed.

Remarks

7. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Knapen et al. (Effect of oral anticoagulant treatment on markers for calcium and metabolism, Haemostasis 30 (6): 290-297 (Nov-Dec 2000)) teach that oral anticoagulants for use in coagulation therapy treatment via administration of Vitamin K antagonists acenocoumarol or phenprocoumon at two different dosages, have effects on Vitamin K-dependent protein markers such as carboxylated osteocalcin in patient blood plasma. These proteins regulate blood coagulation, bone growth, and calcification (Abstract; p. 292, col. 1).

Sokoll et al. (Comparison of biochemical indexes for assessing vitamin K nutritional status in healthy adult population, Am J Clin Nutr 63: 566-573 (1996)) teach using polyclonal antibody specific for carboxylated osteocalcin to determine concentrations of Vitamin K marker and assess the Vitamin K nutritional status of test subjects (p. 567, col. 1).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

July 24, 2009